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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,231	06/20/2002	Philippe Roch	045636-5052	5815
9629	7590	08/16/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP			MINNIFIELD, NITA M	
1111 PENNSYLVANIA AVENUE NW			ART UNIT	
WASHINGTON, DC 20004			PAPER NUMBER	

1645

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM-

Office Action Summary**Application No.**

10/030,231

Applicant(s)

ROCH ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-8 and 11-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 1,3,17 and 18 is/are rejected.
- 7) ☒ Claim(s) 17 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed April 8, 2004 is acknowledged and has been entered. Claims 2, 5, 9 and 10 have been canceled. Claim 1 has been amended. New claim 19 has been added. Claims 1, 3 and 19 are being examined in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or remarks with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 3 and 19 are directed to an allowable (free of the prior art) product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 17 and 18, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 17 and 18 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In accordance with the Official Gazette notice, *supra*, process claims 13, 15 and 16, which do not depend from or otherwise include all the limitations of the allowable product, will NOT be rejoined.
4. Claims 1, 3 and 19 are directed to an allowable (free of the prior art) product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 17 and 18, directed to the process of

making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 17 and 18 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 4, 6-8 and 11-16, not directed to the process of making or using the patentable product, will not be rejoined.

5. This application contains claims 4, 6-8 and 11-16 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Claims 1, 3 and 17-19 are being examined in the present application.

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

8. Claims 1, 3, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. The claims are vague and indefinite in the recitation of "molecular weight"; the claims do not defined how the molecular weight is determined. There are various different methods (i.e. SDS-PAGE, 2-D PAGE, size exclusion chromatography, etc.) known in the art to obtain the molecular weight of a protein or peptide and these methods may give a different value for the molecular weight depending on the method used.

9. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

10. Applicant is advised that should claims 17 and 18 be found allowable, claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 17 and 18 are directed to methods of treating a bacterial, fungal or parasitic infection in a patient or animal comprising administration of an amount of the myticin antimicrobial peptide of claim 1 effective to inhibit further growth of the infectious organism.

The Examiner interprets the claims to read on *in vivo* methods. However, the specification only discloses and teaches *in vitro* methods, *in vitro* activity of antimicrobial effect of the claimed peptides. The specification teaches an *in vitro*

antimicrobial effect of the peptides in a few bacteria, one fungus, and one parasite, not the entire scope of all bacteria, fungus and parasites as presently claimed for the *in vivo* methods. Further, the state of the art does not indicate that there is correlation between the *in vitro* effects and *in vivo* efficacy for treatment of infections caused by the bacteria, fungus and parasite that was shown by in vitro data to be affected by the claimed peptides. The art only teaches in vitro methods, and it is not clear if there is an animal model (see for example Mitta et al, Eur. J. Biochem., 1999, 265:71-78; Mitta et al, J. Cell Science, 2000, 113:2759-2769). The specification indicates that the claimed peptides have no homology with known antimicrobial peptides. Therefore it is not clear that the *in vivo* effects of the claimed antimicrobial peptides would be the same as known antimicrobial peptides in an *in vivo* method.

It is noted that the specification is enabled for in vitro methods of use of the claimed isolated antimicrobial peptides.

12. Claim 19 is allowable.

13. All claims are free of the prior art.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

August 9, 2004